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SECTION 5, 510(k) Summary

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Company Information:

Smiths Medical ASD, Inc.
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Keene, NH 03431
(603) 352-3812, prompt 4, ext 2493
Contact: Brian D. Farias
Regulatory Affairs Manager

JUL 21 2008

Summary Prepared: April 25, 2008

Product Name:

Trade Name: **Saf-T Closed Blood Collection System®**

Common Name: Venous Blood Collection Device

Classification Name: 862.1675 Blood Specimen Collection Device

Predicate Device(s):

K072783 (Smiths Medical ASD, Inc.) Saf-T Closed Blood Collection System® Device

K922445 (Smiths Medical ASD, Inc.- formerly Concord/Portex) Venipuncture Needle Pro® Device

Device Description:

The Saf-T Closed Blood Collection System® device is a venous blood drawing device that is currently used as syringe draw and transfer device to fill vacuum tubes. This submission expands the indications to allow a direct blood draw into a vacuum tube. A syringe draw and transfer remains as an option - the Clinician can choose the method depending upon patient status. The use of this device involves minimal Luer manipulations, which minimizes the risk of sample contamination. This submission also increases the holder length to be equal to similar devices, the longer length will aid in vacuum tube alignment into the holder.

REF Code 99200

Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® Device and Male Luer Connector**

Indications for Use:

The Saf-T Closed Blood Collection System® device is attached to a peripheral IV catheter at the time of IV catheter placement for use as a direct blood draw device into a vacuum tube or to allow a syringe blood draw and transfer to fill vacuum tubes.

REF Code 992XX

Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® and Saf-T Wing® Device**

Indications for Use:

The Saf-T Closed Blood Collection System® device is intended for use as a direct blood draw device into a vacuum tube or to allow a syringe blood draw and transfer to fill vacuum tubes.

Technological Characteristics:

The proposed and predicate devices have the same characteristics, i.e. vascular access via a newly placed IV catheter line or direct access via a safety needle; with tubing and clamps to control blood flow, and a vacuum tube holder for vacuum tube placement.

Non-Clinical Data:

Bench testing confirms that the proposed device and the predicate device have similar performance specifications.

Clinical Data:

Not Required

Conclusion:

The bench testing conducted demonstrates that the proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Brian D. Farias
Regulatory Affairs Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2008

Mr. Brian Farias
Regulatory Affairs Manager
Smiths Medical ASD, Incorporated
10 Bowman Drive
Keene, New Hampshire 03431

Re: K081229
Trade/Device Name: Saf-T Closed Blood Collection System®
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA
Dated: April 25, 2008
Received: April 30, 2008

Dear Mr. Farias:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

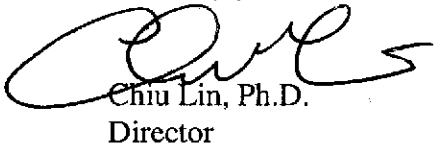
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a ~~legally marketed predicate device results in a classification for your device and thus, permits~~ your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K081229

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

REF Code 99200

Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® Device and Male Luer Connector**

Indications for Use:

The Saf-T Closed Blood Collection System® device is attached to a peripheral IV catheter at the time of IV catheter placement for use as a direct blood draw device into a vacuum tube or to allow a syringe blood draw and transfer to fill vacuum tubes.

REF Code 992XX

Device Name: **Saf-T Closed Blood Collection System® with Saf-T Holder® and Saf-T Wing® Device**

Indications for Use:

The Saf-T Closed Blood Collection System® device is intended for use as a direct blood draw device into a vacuum tube or to allow a syringe blood draw and transfer to fill vacuum tubes.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page _1_ of _1__

for Chulin

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K081229